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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/588,718

05/15/2007

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EXAMINER

SUTTON, DARRYL C

ART UNIT

PAPER NUMBER

1612

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/588,718	Applicant(s) ARNOLD ET AL.	
	Examiner DARRYL C. SUTTON	Art Unit 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 15-52 is/are pending in the application.
- 4a) Of the above claim(s) 5,8-12,15-17,19-27,29-36,38-48,50 and 52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,6,7,18,28,37,49 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is in response to the amendment filed 10/06/2008. No new claims have been added. Claim 13 has been cancelled.

Applicant's arguments filed 10/06/2008 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Election/Restrictions

Applicant alleges that the Examiner is not correct in examining claims 1-4, 6-13, 18-32, 37, 49 and 51 as elected Group IV, i.e., claims 11, 12, 25 and 26 should not have been withdrawn from consideration. Claims 11 and 12 both depend on claim 4 and limit the pendant phenyl moiety to being incorporated into a multi-ring system. Applicant made the specific election of polystyrene as (d) the polymer in the Response to Restriction filed 02/21/2008 and the pendant phenyl moiety of polystyrene is not part of a multi-ring system as required by claims 11 and 12, therefore claims 11, 12, 25 and 26 are properly withdrawn.

Claim Rejections - 35 USC § 112

Claims 49 and 51 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is maintained.

Applicant argues that the specification provides data for a cyano-modified chloromethyl styrene and an ethoxy-modified chloromethyl styrene polymer and also describes chloromethylated polystyrene cross-linked with divinylbenzene as NO-releasing polymers.

This disclosure is insufficient, since the term "NO-releasing polymer" may encompass a large number of polymers with substantial variance. Therefore, the disclosure of 3 styrene and polystyrene polymers does not comply with the written description as argued by Applicant; and since the disclosure of only 3 polymers makes it doubtful that Applicant was in possession of a reasonably representative set of polymers that would be "NO-releasing" at the time of the invention.

Claim Rejections - 35 USC § 103

Claims 1 and 2 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cafferata (U.S. 2003/0083739) in view of Arnold et al. (Nitric oxide, 2002).

The rejection is maintained.

Applicant argues that Cafferata teaches a 2 disparate drug delivery system that combines the systemic delivery of a non-toxic, sub-threshold dose of a drug with a targeted delivery of a second drug using a catheter mediated stent, and therefore does not teach the claimed composition.

The Examiner disagrees.

As disclosed in the Office action dated 07/07/2008, Cafferata teaches delivery of NO-releasing compounds which are bound as pendant groups attached to polymers such as polystyrene, See page 7. Further, Applicant's claim is drawn to a composition "comprising" a compound attached to at least one phenyl containing polymer. The word "comprising" is open-ended and contemplates additional components of the composition.

Applicant argues that Arnold does not teach or even suggest attaching the disclosed compounds to a phenyl-containing polymer, much less the compound as recited by amended claim 1.

The Examiner disagrees.

Arnold teaches carbon-bound diazeniumdiolate molecules which are NO-releasing compounds. Therefore, it would have been obvious to one of ordinary skill in the art to modify the composition of Cafferata to include the compounds of Arnold based on their suitability for the intended use, i.e. NO-releasing compound. See MPEP 2144.07.

Claims 3, 4, 6, 7, 18, 28, 37, 49 and 51 were rejected under 35 U.S.C. 103(a) as being unpatentable over Cafferata (U.S. 2003/0083739) in view of Arnold et al.(b) (Organic Letters, 2002) and further in view of Arnold et al.(a) (Nitric Oxide, 2002).

The rejection is maintained.

Applicant argues that since claim 1 is not rejected in this section of the Office Action the rejection is proper.

The Examiner disagrees.

The Examiner's response to arguments concerning claim 1 are provided above. Since claim 1 is properly rejected in the previous rejection, it need not be rejected in this section, although the prior art and reasoning for the rejections do apply to claim 1.

Applicant argues that the assertion that the compound of Arnold (b) does not read on the compound recited in claim 3.

The Examiner disagrees.

Arnold et al.(b) teaches a compound comprised of, 3-x, $\text{N}_2\text{O}_2\text{Na}$ moieties, where $x = 0-2$ in equation (1) of scheme 2. Therefore, the compound is comprised of between 1 and 3 $\text{N}_2\text{O}_2\text{Na}$ moieties; the compound is also comprised of a cyano, CN, group. And, Arnold teaches that one or more diazeniumdiolate groups initially form on acetonitrile in equation 1, and in the presence of methoxide and methanol the cyano group is converted to an imidate as in equation (2), (page 1324, 2nd column, 2nd paragraph). Therefore, it is well within the purview of the skilled artisan to produce compounds as claimed in the instant application without converting them using reaction (2). Since Arnold et al.(a) teaches that carbon-bound diazeniumdiolate compounds comprised of 2

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diazoniumdiolate moieties are NO-releasing compounds and do not produce carcinogens, it would reasonably be expected that the compound of Arnold et al. (b), where $x = 1$, i.e. a compound with a cyano group and 2 $\text{N}_2\text{O}_2\text{Na}$ moiety would also be NO-releasing and therefore, could be combined with Cafferata in a modified composition. Therefore, the combination suggested by combining Cafferata, Arnold et al.(a) and Arnold et al.(b) reads on the medical devices of claims 49 and 51

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612